

**REMARKS/ARGUMENTS**

Claims 60-64, 69, and 70 were examined. The claims have been amended as noted above. Re-examination and reconsideration of the claims, as amended, are respectfully requested.

Applicants thank Examiner Nguyen for the helpful and courteous interview on October 15, 2008. At that interview, Applicants discussed the differences between the Evans '487 publication and the claims of the present application. Briefly, Applicants explained that Evans includes a pair of counter-rotating shearing elements. These shearing elements are not opened by a balloon and will not radially penetrate the occlusive material that they are shearing. The Examiner suggested that to better differentiate Evans, Applicants might amend independent claim 60, the only remaining independent claim, to positively recite that the balloon is inflated in order to effect radial expansion of the scoring structure. Applicants have so amended claim 60.

Claims 60-64, 69 and 70 were rejected overly newly cited U.S. Patent Publication No. 2002/0010487 to Evans in combination with previously cited U.S. Patent No. 5,102,402, to Dror. Such rejections are traversed in part and overcome in part.

Independent claim 60, the only pending independent claim, even prior to amendment recited that a lesion is scored by metal scoring elements carried by an expansible balloon. The Examiner relies on Evans, Figs. 2-4 as teaching the scoring of a lesion with metal scoring elements 30 carried by an expansible balloon (see paragraphs 68 and 80). Applicants respectfully disagree with this characterization of Evans. Figs. 2-4 clearly illustrate a shearing cage structure 28 comprising a pair of counter-rotating helical blades 18 and 20. While these blades may be radially expanded, such radial expansion is provided by axially foreshortening the scoring cage structure, not by balloon expansion. While the Evans publication does contemplate the combination of the shearing structure with a balloon, the balloon is intended to isolate a treatment region, not expand the scoring blades. In paragraph 80, a balloon is taught specifically to provide distal protection, again, not being relied on to expand or otherwise interact with the shearing blades.

For these reasons, Examiner's reliance on Evans is misplaced.

Even if Evans were somehow considered relevant, its combination with Dror is difficult to contemplate. Again, Evans discloses a shearing catheter intended to be expanded within thrombus in order to shear the thrombus from the vessel wall. While drugs could be introduced by providing balloon occlusion on either side of the shearing structure, the drugs would necessarily be in liquid (or at least be in a flowable form) in order to be mixed by the shearing blades, particularly for dissolving the sheared thrombus.

The delivery catheter of Dror, contrast, shows a balloon having a plurality of frangible microcapsules on its outside for delivery into a blood vessel wall. There would be no reason to provide such microcapsules on the shearing blades of Evans, and if the drug microcapsules were so placed, it is difficult to contemplate how they could be effective. Moreover, the microcapsules on the balloon could not be substituted for the drug injection teachings of Evans since the microencapsulated drugs on the balloon surface would not be available to be mixed with the shearing blades to dissolve the clot in thrombus.

Nonetheless, in order to further distinguish the teachings of Evans, Applicants have amended independent claim 60 to clarify that the scoring elements carried on the balloon are caused to "radially penetrate the stenotic material." At best, Evans suggests an annular shearing of thrombus and no teaching or suggestion of radial penetration is provided.

For these reasons, it is believed that independent claim 60, as well as all claims dependent thereon, clearly distinguish the teachings of Evans even when combined with those of Dror.

### **RELATED PATENT APPLICATIONS**

Parent application number 10/631,499 includes claims directed at a particular scoring catheter having helical scoring elements which circumscribe a balloon or other expansible shell. The application also includes claims directed at methods for scoring stenosed regions using such cage as having helical scoring elements. These claims were rejected in a final office action mailed on June 3, 2008, by Examiner Nguyen. Applicants will be responding to this office action in due course.

Co-pending application 10/399,589, has a non-final office action which was mailed on July 9, 2008, and is being handled by Examiner Ryckman. In that application, claims directed at angioplasty balloon catheters comprising a shaft and the non-deployable stent which is attached to the shaft by rings, have been rejected as being obvious over the teachings of U.S. Patent No. 6,053,913 to Tu in view of U.S. Patent No. 6,106,584 to Roubin. Applicants continue to traverse these rejections and will be filing a response in that application in due course.

Co-pending application 11/292,426, which is a continuation-in-part of 10/399,589, includes claims directed at angioplasty catheters and methods for performing angioplasty. All claims were rejected over U.S. Patent No. 6,190,403 to Fischell. A response to this office action will be filed in due course.

CONCLUSION

In view of the above amendments and remarks, Applicants believe that all pending claims are in condition for allowance and request that the application be passed to issue at an early date.

If for any reason the Examiner believes that a telephone conference would in any way expedite prosecution of the subject application, the Examiner is invited to telephone the undersigned at 650-326-2400.

Respectfully submitted,

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